Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

ent FEB 15 2007

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Sept WC Wound Cleanser
ssified

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, 2006

ion 510(k) premarket notification of intent to market the device
etermined the device is substantially equivalent (for the indications for
o legally marketed predicate devices marketed in interstate commerce
nactment date of the Medical Device Amendments, or to devices that
ordance with the provisions of the Federal Food, Drug, and Cosmetic
approval of a premarket approval application (PMA). You may,
subject to the general controls provisions of the Act. The general
t include requirements for annual registration, listing of devices, good
ling, and prohibitions against misbranding and adulteration.

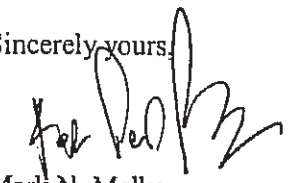
ee above) into either class II (Special Controls) or class III (PMA), it
ional controls. Existing major regulations affecting your device can
eral Regulations, Title 21, Parts 800 to 898. In addition, FDA may
nts concerning your device in the Federal Register.

s issuance of a substantial equivalence determination does not mean
ination that your device complies with other requirements of the Act
egulations administered by other Federal agencies. You must comply
nts, including, but not limited to: registration and listing (21 CFR Part
801); good manufacturing practice requirements as set forth in the
ion (21 CFR Part 820); and if applicable, the electronic product
(Sections 531-542 of the Act); 21 CFR 1000-1050.

egin marketing your device as described in your Section 510(k)
DA finding of substantial equivalence of your device to a legally
ults in a classification for your device and thus, permits your device

or your device on our labeling regulation (21 CFR Part 801), please
nce at (240) 276-0115. Also, please note the regulation entitled,
premarket notification" (21CFR Part 807.97). You may obtain other
esponsibilities under the Act from the Division of Small
nd Consumer Assistance at its toll-free number (800) 638-2041 or
et address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

own):

t WC Wound Cleanser

nd the removal of foreign material and debris from
irty wounds, abrasions and minor irritations, cuts, exit sites,

(____ AND/OR Over-The-Counter Use _____
Subpart D) (21 CFR 801 Subpart C)

WRITE BELOW THIS LINE-CONTINUE ON ANOTHER
PAGE IFNEEDED)

nce of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K061467

lotification

Back To Search Results

on Name	Dressing, Wound, Drug
	K061467
	EXSEPT WC WOUND CLEANSER
	ALCAVIS INTERNATIONAL, INC. 8322 Helgerman Court Gaithersburg, MD 20877
	Gary J Mishkin
uct Code	FRO
	05/26/2006
	02/15/2007
	Substantially Equivalent (SE)
sory Committee	General & Plastic Surgery
ommittee	General & Plastic Surgery
y/Purged Status	Summary Only
	Summary
	Traditional
Party	No
	No